DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 7, 2015

Jeisys Medical Incorporated
% Ms. Priscilla Chung
LK Consulting Group USA Incorporated
2651 East Chapman Avenue, Suite 110
Fullerton, California 92831

Re: K141861
Trade/Device Name: Hilthera 4.0 Therapeutical Laser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: July 3, 2014
Received: July 10, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141861

Device Name

Hilthera 4.0 Therapeutical Laser System

Indications for Use *(Describe)*

To provide topical heating for the purpose of elevating tissue temperature for temporary relief of muscle and joint pain and stiffness, arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

1. Submission Sponsor

Jeisys Medical, Inc.
307 Daeryung Techno Town 8th
Gamasan-ro 96, Geumcheon-Gu, Seoul
153-775
Korea
Phone: (82) 2.2603.6417
Fax: (82) 2.2603.6447
Contact: kyung won- Hwang, RA Manager

2. Submission Correspondent

Priscilla Chung
LK Consulting Group USA Inc.
2651 E Chapman Ave Ste 110,
Fullerton CA 92831
Email: juhee.c@lkconsultinggroup.com

3. Date Prepared

November 18th, 2014

4. Device Identification

Trade/Proprietary Name:	Hilthera 4.0 Therapeutical Laser System
Common/Usual Name:	ND:YAG Laser
Classification Regulation:	890.5500
Product Code:	ILY
Device Class:	Class II
Classification Panel:	Infrared Lamp

5. Predicate Devices

El En SpA – El En HILT Family Laser, K051537

6. Device Description

- Device Specification

A complete device specification is included in attachment 11 and in the Operator's Manual located in attachment 13 of this submission.

- Labeling / instructions for use

Complete labeling is located in attachment 13

- Use principles
Use principles are provided in the Device Description located in attachment 13

7. Intended Use

To provide topical heating for the purpose of elevating tissue temperature for temporary relief of muscle and joint pain and stiffness, arthritis pain or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

8. Comparison of Technological Characteristics

The Hilthera 4.0 device shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices. The Hilthera 4.0 device is similar in design and function to the predicate devices for the modes of operation and use.

The devices have a control unit that can be programmed utilized for the patient parameters. In addition, they are equipped with manual interface, enabling to operate the device during therapy, and a display, which shows the set and indicated parameters. During operation the devices have an applicator instrument attached to the main unit.

9. Substantial Equivalence Discussion

The following table compares the Hilthera 4.0 device to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**El En SpA**	**Jeisys Medical, Inc.**
Trade Name	Predicate HILT Family Laser	New Device Hilthera 4.0
510(k) Number	K051537	Not assigned
Intended Use	To provide topical heating for the purpose of elevating tissue temperature for temporary relief of muscle & joint pain & stiffness, arthritis pain or muscle spasm; the temporary increase in local blood circulation and/or promoting relaxation of muscle.	To provide topical heating for the purpose of elevating tissue temperature for temporary relief of muscle & joint pain & stiffness, arthritis pain or muscle spasm; the temporary increase in local blood circulation and/or promoting relaxation of muscle.
Energy Source	ND:YAG laser	ND:YAG laser
Laser mode	Pulsed(PW)	Pulsed(PW)

Manufacturer	**El En SpA**	**Jeisys Medical, Inc.**
Trade Name	Predicate HILT Family Laser	New Device Hilthera 4.0
Wave length	1064nm	1064nm
Power Source	230 VAC, 15A, 50/60 Hz	230 VAC, 50/60 Hz
Power/Energy Range	Maximum 10W	Maximum 10W
Fluence	0.15~0.45 J/cm^2	0.15~1.2 J/cm^2
Pulse width	60-150us	100-150us
Repetition rate	10-40 Hz	10-30 Hz
Spot size	Ø 5mm 0.2 cm^2	Ø 5mm *0.2 cm^2*
Delivery System	Contact and Non-contact hand pieces connected to the system via a 600 um diameter fiber optic cable	Contact hand pieces connected to the system via a 1000 um diameter fiber optic cable
Aiming Beam	Diode 655nm (Red) 1mW	Diode 655nm (Red) 1mW
Weight	40 kG	80 kG
Dimensions	30 cm x 70 cm x 78 cm	*40 cm x 92.1 cm x 128.2* cm

10. Non-Clinical Performance Data

The device's hardware and software development, verification, and validation have been carried out in accordance with FDA guidelines. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The Device Hazard analysis was completed and risk control implemented to mitigate identified hazards. The testing result supports that all the hardware specifications and software specifications have met the acceptance criteria of each module and interaction of processes. The Hilthera 4.0 device passed all testing and supports the claims of substantial equivalence and safe operation.

The Hilthera 4.0 device complies with the applicable voluntary standards for Electromagnetic Compatibility and Safety. The device passed all the electrical and safety testing according to national and international standards.

11. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate devices. The verification and validation testing of the device software and electrical safety and EMC testing of the device was found to acceptable and supports the claims of substantial equivalence.

12. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the difference between the Hilthera 4.0

device and the predicate device do not raise any questions regarding its safety and effectiveness. The Hilthera 4.0 device, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.

13. Conclusion

The Hilthera 4.0 device has similar intended use and technological characteristics as the predicate devices.

The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators.